MAR 8 2002

K014052
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510(k) Summary, Safety and Effectiveness

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, California 92614 USA
Contact:	Jason Smith Phone: 949-250-2662 Fax: 949-250-3579
Device Trade Name:	Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material
Common Name:	Percutaneous Sheath Introducer
Classification:	Class II (Reference 21 CFR 870.1340)
Predicate or Legally Marketed Device:	Baxter Hemostasis Valve Introducers Baxter Healthcare Intro-Flex® Sheath Introducers with AMC Thromboshield Baxter Healthcare Vantex™ Central Venous Catheters with Oligon™ material
Date prepared:	December 6, 2001

Device Description:

The Baxter Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are used to access the venous system and to facilitate catheter insertion. The introducers are composed of a housing body to which a sheath is attached distally and a side port/extension tube is connected proximally. The sheath is composed of Oligon™ a polyurethane-based antimicrobial material. (Silver is the antimicrobial agent.) A valve is located in the housing body to provide a seal around a catheter when inserted through the Introducer and to prevent backflow when no catheter is present. A dilator is provided with the Introducer to ease insertion of the device into the vessel. The device will be packaged in a tray sealed with a tyvek lid and sterilized using 100% ethylene oxide.

Indications for Use:

The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

Technology Comparison:

The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are technologically comparable to the predicate devices in construction and physical specifications. Furthermore, design, manufacturing, and sterilization procedures are representative of current industry practices.

Test Summary, *In-vitro*:

Functional testing was performed on the Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material to evaluate the integrity and performance of the device. Based upon the results of this testing, Edwards Lifesciences has determined that the Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are safe and effective and are acceptable in design and construction for their intended use.

Test Summary, *In-vivo*:

Clinical testing was not performed on the subject device because the intended use and indications are the same as the predicate devices. Furthermore, the Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material exhibited comparable design characteristics to the predicate devices in the *in vitro* testing, thus clinical testing was not performed.

Test Summary, Biocompatibility:

Biocompatibility testing was performed on the Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material in accordance with the requirements specified in International Standards Organization (ISO) 10993-1-1994 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests and the FDA General Program Memorandum No. G95-1. The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material were found to be biocompatible and nontoxic and acceptable for its intended use.

Rationale for Substantial Equivalence Determination:

The battery of non-clinical tests discussed above demonstrates that the Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material exhibit comparable mechanical and functional characteristics to the predicate devices in addition to being biocompatible and chemically acceptable. Based upon those characteristics, the Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are substantially equivalent to the predicate devices in safety and effectiveness in addition to being intended for the same uses.

Jason Smith 12/16/01

Jason Smith Date
Senior Regulatory Affairs Specialist
Edwards Lifesciences LLC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Mr. Jason Smith
Sênior Regulatory Affairs Specialist
Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92614-5686

Re: K014052
Percutaneous Sheath Introducer
Regulation Number: 870.1370
Regulation Name: Catheter tip occluder.
Regulatory Class: Class II
Product Code: DYB
Dated: December 6, 2001
Received: December 10, 2001

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

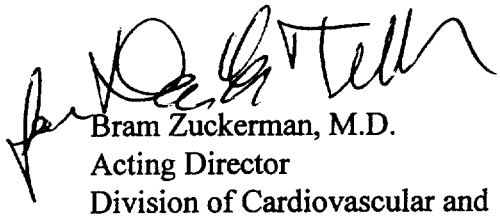
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K01 4052

Device Name: Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material

Indications For Use:

The Edwards Lifesciences Percutaneous Sheath Introducers with Oligon™ material are indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

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(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014052